

MILESTONE STATUS OF OTC DRUG REVIEW DOCUMENTS AS of January 13, 2005			
DRUG CATEGORY	ANPR	PR	FR/FM
	Advance Notice of Proposed Rulemaking or Panel Report	Notice of Proposed Rulemaking or Proposed Rule	Final Rule/Final Monograph
Acne	3/23/82	1/15/85 8/7/91	8/16/91
Alcohol		10/21/93	3/13/95
Exempt IPECAC Max. Conc. Limits		5/10/96	11/18/96
Anorectal	5/27/80	8/15/88	8/3/90
310.545 Listing (LYCD)			9/2/93
Witch Hazel Name Change			6/3/94
Hydrocortisone/Pramoxine HCl Combination			8/26/03
Antacid	4/5/73	11/12/73	6/4/74
In Vitro Test		5/27/80	8/31/82
Statement of Identity/Upset Stomach		9/21/79	8/31/82
Exemption/Accidental Overdose		4/13/84	8/1/86
Combo/Antacid & Analgesic		11/16/88	
Relief of Upset Stomach/Overindulgence		12/24/91	
Drug Interaction Precaution		7/30/86	8/26/93
USP Testing Procedures		9/23/93	2/8/96
Sodium Bicarbonate Warning		2/2/94	
Anthelmintic	9/9/80	8/24/82	8/1/86
Antibiotics (First aid)	4/1/77	7/9/82	12/11/87
Technical			5/25/88
Anesthetics in Aerosols		8/18/89	3/15/90
Revised Standards for BA/PO Aerosols		5/11/90	10/3/90
Anesthetics		6/8/90	12/5/90
Allergy Warning		2/14/96	11/15/96
Anticaries	3/28/80	9/30/85 6/15/88	10/6/95 10/6/95
Partial Delay of Effective Date			10/7/96
Partial Stay of Regulation; Enforcement Policy			12/16/96
Antidiarrheal	3/21/75	4/30/86	4/17/03
Amend Add Traveler's Diarrhea		4/17/03	5/12/04
Antiemetic	3/21/75	7/13/79 8/26/93	4/30/87 4/11/94
Diphenhydramine Labeling		8/29/97	12/6/02
Antiflatulent	4/5/73	11/12/73	6/4/74
Exemption/Accidental Overdose		4/13/84	8/1/86
Statement of Identity		1/29/88	3/5/96
Antifungal	3/23/82	12/12/89	9/23/93
Diaper Rash@	9/7/82	6/20/90	12/18/92
Nails and Scalp	3/23/82	12/12/89	9/2/93

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Amend Indications		7/22/99	8/29/00
Clotrimazole		5/29/01	2/8/02
Antimicrobials/Alcohols (Topical)	5/21/82	7/22/91	NA
Antimicrobials/Antiseptics (Health Care)	9/13/74	1/6/78 6/17/94	
Antimicrobials/Diaper Rash@	9/7/82	6/20/90	
Antimicrobials/Mercurials	1/5/82	7/22/91	4/22/98
Antiperspirant	10/10/78	8/20/82	6/9/03
Partial Stay			10/15/04
Antiseptics (First aid)	9/13/74	1/6/78 7/22/91	
Aphrodisiac	10/1/82	1/15/85	7/7/89
Benign Prostatic Hypertrophy	10/1/82	2/20/87	2/27/90
Boil Treatment	6/29/82	1/26/88	11/15/93
Camphorated Oil	9/26/80	NA	9/21/82
Category II/III Ingredients (Phase I)	NA	5/16/90	11/7/90 1/30/92
Category II/III Ingredients (Phase II)	NA	8/25/92	5/10/93
Category II/III Ingredients (Certain Additional)		NA	4/22/98 8/24/98 5/9/02 5/9/02
Cholecystokinetic	2/12/80	8/24/82	6/10/83
Soybean Oil		8/15/88	2/28/89
Cold/Cough/Anticholinergic	9/9/76	7/9/82	11/8/85
Cold/Cough/Antihistamine	9/9/76	1/15/85 8/24/87	12/9/92 12/9/92
Amend to FR Doxylamine			1/28/94
Amend to FR Diphenhydramine			4/9/96
Diphenhydramine Labeling		8/29/97	
Reopening of Admin. Record (colds)		8/25/00	12/6/02
Cold/Cough/Antitussive	9/9/76	10/19/83	8/12/87
Exempt Menthol Lozenges from Overdose Warning		7/6/89	7/6/90
Amend to Use the Term Lozenge		10/2/89	6/3/90
MAOI Drug Interact. Warn. Dextromethorphan		6/19/92	10/20/93
Include Diphenhydramine		12/9/92	4/9/96
Diphenhydramine Labeling		8/29/97	12/6/02
Flammability Warning		7/20/98	8/1/00
Cold/Cough/Bronchodilator	9/9/76	10/26/82	10/2/86
MAOI Drug Interaction Warning		6/19/92	10/20/93
Remove Ephedrine from Market		7/27/95	
Remove Aerosol Epinephrine		3/9/95	5/20/96

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Cold/Cough Combinations	9/9/76	8/12/88 11/14/88	12/23/02
Diphenhydramine Combinations		2/23/95	4/9/96
Theophylline Combinations			7/27/95
Bronchodilator Combinations			9/27/01
Cold/Cough/Expectorant	9/9/76	7/9/82	2/28/89
Updating/Tech. Changes			6/30/92
310.545 Listing			9/14/92
Cold/Cough/Nasal Decongestant	9/9/76	1/15/85	8/23/94
Levmetamfetamine (formerly l-desoxyephedrine)			3/8/96 7/30/98
Sinusitis Labeling		8/2/04	
Phenylephrine Bitartrate		11/2/04	
Corn/Callus Remover	1/5/82	2/20/87	8/14/90
Dandruff/Seborrhea/Psoriasis	12/3/82	7/30/86	12/4/91
Micronized Selenium Sulfide		4/5/93	1/28/94
Daytime Sedative	12/8/75	6/13/78	6/22/79
Deodorants (Internal)	1/5/82	6/17/85	5/11/90
Digestive Aids	1/5/82	1/19/88	10/21/93
Eligibility Criteria (Additional Conditions)	10/3/96	12/20/99	1/23/02
Exocrine Pancreatic Insufficiency	12/21/79	11/8/85 7/15/91	4/24/95 4/24/95
External Analgesic	12/4/79	2/8/83	
Hydrocortisone 1% Amend. of TFM		2/27/90	
Patch, Plaster, and poultice dosage forms		7/17/03	
Diphenhydramine Labeling		8/29/97	12/6/02
Diaper Rash	9/7/82	6/20/90	12/18/92
Fever Blister/Cold Sore (Ext.)@@	9/7/82	1/31/90	
Insect Bites/Stings & Poison Ivy/Oak/Sumac	9/7/82	10/3/89	
Male Genital Desensitizers	9/7/82	10/2/85	6/19/92
Fever Blister/Cold Sore (Internal)	1/5/82	6/17/85	6/30/92
Hair Grower/Loss	11/7/80	1/15/85	7/7/89
Hexachlorophene	1/7/72	NA	9/27/72
Hormone (topical)	1/5/82	10/2/89	9/9/93
Hypo/Hyperphosphatemia	12/9/80	1/15/85	5/11/90
Ingrown Toenail Relief	10/17/80	9/3/82 / 10/4/02	9/9/93
Insect Repellents (Internal)	1/5/82	6/10/83	6/17/85
Internal Analgesic	7/8/77	11/16/88	
Overindulgence		12/24/91	
Ibuprofen and Labeling		8/21/02	
Consumer Warning (Professional Uses of ASA)		10/20/93	

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Professional Labeling of Aspirin Products		6/13/96	10/23/98
Technical Amend.			9/14/99
Leg Muscle Cramps	10/1/82	11/8/85	8/22/94
Malaria		4/19/95	3/20/98
Sodium Bicarbonate Warning		2/2/94	
Labeling Regulations			
Sodium Labeling		4/25/91 3/24/04	4/22/96 11/29/04
Partial Delay of Effective Date			4/24/97
Technical Amendment/Termination of Delay of Effective Date			3/24/04
Reye Syndrome Warning for Other Salicylates		10/20/93	
Calcium, Magnesium, and Potassium		4/22/96	3/24/04
Alcohol Warning		11/14/97	10/23/98
Alcohol Warning; Compliance Date			3/17/99
Labeling Requirements		2/27/97	3/17/99
Correction			4/15/99
Technical Amendment			1/3/00
Partial Extension of Compliance Dates			6/20/00
Guidance for Industry/Column Format		12/1/99	12/19/00
Guidance for Industry/Exemptions & Deferrals		12/19/00	10/18/02
Guidance for Industry/ANDA Labeling		2/22/01	10/18/02
Partial Delay of Compliance Dates			4/5/02
Delay of Implementation Date (Sunscreen Products)			9/3/04
Compliance Guidance for Small Business Entities on Labeling OTC Drug Products		12/9/04	
Guidance for Industry on labeling OTC Drug Products (Questions and Answers)		1/13/05	
Guidance for Industry on Drug Products Containing Ensulizole, Hypromellose, Meradimate, Octinoxate, and Octisalate – Labeling Enforcement Policy			6/3/03
Laxative	3/21/75	1/15/85	
Bulk/ Amend to PR		10/1/86 8/5/03	
Docusate Salts/ Amend to PR		9/2/93	
Sodium Phosphates Package Size		3/31/94	5/21/98
Danthron and Phenolphthalein		9/2/97	1/29/99
Sodium Phosphates Labeling		5/21/98	12/9/98 (WD)

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Stimulant Laxatives		6/19/98	
Rectal Sodium Phosphates Labeling Stay			12/7/98
Menstrual Products	12/7/82	11/16/88	
Nailbiting/Thumbsucking Deterrent	10/17/80	9/3/82	9/2/93
Nighttime Sleep/aid	12/8/75	6/13/78	2/14/89
Diphenhydramine Labeling		8/29/97	12/6/02
Standardize Diphenhydramine Warnings		8/26/93	4/11/94
Diphenhydramine Labeling		8/29/97	12/6/02
Ophthalmic	5/6/80	6/28/83	3/4/88
Ophthalmic/Anti-infective			12/18/92
Add/Revise Warnings		2/23/98	6/21/00
Technical Amendment (Eyewashes)			2/19/03
Emergency First Aid Use		2/19/03	
Technical Amendment (Name Change)			6/3/03
Oral Health Care			
Antiseptic	5/25/82	2/9/94	
Non/Antimicrobial	5/25/82	1/27/88 (1st Segment)	
Plaque/Gingivitis	5/29/03		
Oral Discomfort (Relief)	5/25/82	9/24/91 (2nd Segment)	
Amend. Menthol Lozenge		5/13/92	
Oral Mucosal Injury	11/2/79	7/26/83	
Oral Wound Healing	11/2/79	7/26/83	7/18/86
Otic (Earwax Removal)	12/16/77	7/9/82	8/8/86
Otic (Swimmer's Ear)	12/16/77	7/30/86	2/15/95
Partial Stay/Water/Clogged Ear Claim			8/16/95
Water/Clogged Ears/Lift Partial Stay		8/17/99	8/10/00
Overindulgence Remedies	10/1/82	12/24/91 1/5/05	
Reye Syndrome Warning		5/5/93	
Remedies/Prevents Inebriation	10/1/82	NA	7/19/83
Pediculicides	6/29/82	4/3/89	12/14/93
Technical Amendment			8/13/98
Add/Revise Labeling		5/10/02	12/31/03
Poison Treatment			
Emetic Drug Products	3/21/75	9/5/78	
Acute Toxic Ingestion Treatment/Emetic	1/5/82#	1/15/85#	
Salicylanilides (TBS)	9/13/74	NA	10/30/75
Silver		10/15/96	8/17/99
Skin Bleaching	11/3/78	9/3/82	
Skin Protectant	8/4/78	2/15/83	

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Technical Amendment			12/9/03
Technical Amendment			8/19/04
Astringents@@	9/7/82	4/3/89 6/13/03	10/21/93
Astringents Revise Labeling			10/9/03
Insect Bites/Stings & Poison Ivy/Oak/Sumac	9/7/82	10/3/89	
Diaper Rash@	9/7/82	6/20/90	
Fever Blister/Cold Sore@@	9/7/82	1/31/90	
Smoking Deterrent	1/5/82	7/3/85	6/1/93
Stimulant	12/8/75	6/13/78	2/29/88
Hangover Claim		12/24/91	
Stomach Acidifier	10/19/79	1/15/85	8/17/88
Sunscreen	8/25/78	5/12/93	5/21/99
Include Only USP Ingredients		6/8/94	5/21/99
Include Avobenzone		9/16/96	5/21/99
Include Zinc Oxide		10/30/97	5/21/99
Extend Effective Date			6/8/00
Partial Stay			12/31/01
Names Amendment			6/20/02
Sweet Spirits of Nitre	2/22/80	NA	6/27/80
Vaginal Contraceptive	12/12/80	2/3/95	
Required Labeling		1/16/03	
Vaginal Drug Products	10/13/83	NA	2/3/94 (WD)
Vaginal (Yeast Infections)	7/16/98		
Vitamin/Mineral	3/16/79	NA	11/27/81(WD)
Wart Remover	10/3/80	9/3/82 3/27/87 1/28/94	8/14/90 8/14/90 11/23/94
Weight Control	2/26/82	10/30/90	
Certain Ingredients			8/8/91
Water Soluble Gums		10/30/90	8/26/93
PPA Labeling		2/14/96	
Zirconium (Aerosol)	6/5/75	NA	8/16/77

Separate publications that include: Emetic and Acute Toxic Ingestion

Note: N/Notice; WD/Withdrawn; NA/not applicable.

@ See: Antifungal, Antimicrobial, External Analgesic, and Skin Protectant

@@ See: External Analgesic and Skin Protectant